



April 19, 2012

The Honorable Edward J. Markey
House of Representatives
2108 Rayburn House Office Building
Washington, DC 20515-2107

Re: Food Additive Petition (FAP) No. 2B4793

Dear Representative Markey:

This is in reference to your petition, FAP No. 2B4793, proposing that 21 CFR §177.1580 and §177.1585 of the food additive regulations be amended to no longer provide for the use of Bisphenol A (BPA) based polycarbonates and polyester carbonates in small reusable household food and beverage containers because these uses have been abandoned. We are not filing this petition for the reasons discussed below.

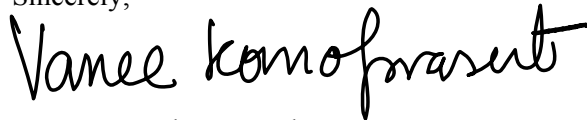
Under 21 CFR 171.130, a petitioner may propose that FDA amend a food additive regulation if the petitioner can demonstrate that there are “old uses abandoned” for the relevant food additive. Such abandonment must be complete for any intended uses in the U.S. market. A petition must include data to demonstrate its assertion that the specific uses mentioned in the petition have been abandoned, as required by 21 CFR 171.130(b). The agency has determined that the petition is not suitable for filing because it does not include evidence to demonstrate that a significant percentage of the market has abandoned the food additives uses that are the subject of this petition. In Section II, the petition references a December 2011 survey of identifiable manufacturers of small reusable household food and beverage containers. You provided copies of the survey letters to 7 manufacturers and their response letters. Importantly, you did not provide a rationale how these manufacturers were identified and whether they represent a complete survey of all manufacturers, or a significant percentage of manufacturers, both in the US and worldwide intended for sale in the U.S. The majority of the companies that were the subject of your limited survey indicated that they had never used BPA-based PC resins to manufacture their products. This data would therefore not represent the types of information required under 21 CFR 171.130(b) to establish evidence of abandoned old uses of BPA-based PC resins. The petition contains no evidence demonstrating that the major PC resin manufacturers and converters no longer sell their resins for use in the manufacture of small reusable houseware food and beverage containers. Moreover, the petition contains no evidence that the major retailers of small reusable houseware food and beverage containers no longer stock these products. Because the petition does not include data to support your assertion that the use of BPA based materials in small reusable household food and beverage containers has been completely abandoned, we have concluded that the petition does not contain data to adequately demonstrate that the specific uses mentioned in the petition have been abandoned as required by 21 CFR 171.130 (b) and therefore is not suitable for filing.

We will retain this petition in our inventory of inactive petitions, and we will not take any further action on your current proposal. You may submit a new petition that contains information that address the deficiencies noted above, whenever it becomes available. Should you do so, you need not resubmit the

information in Petition No. 2B4793; rather, you may explicitly reference the information in Petition No. 2B4793 in any subsequent petition you choose to submit.

If you have any questions concerning this matter, please do not hesitate to contact us.

Sincerely,

A handwritten signature in black ink that reads "Vane Komolprasert". The signature is fluid and cursive, with the first name "Vane" and last name "Komolprasert" clearly distinguishable.

Vane Komolprasert, Ph.D., P.E.
Consumer Safety Officer
Division of Food Contact Notifications, HFS-275
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition